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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/214,723 01/11/99 OKA

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EXAMINER

SISSON,B

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

11/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/214,723

Applicant(s)

TAKANORI OKA

Examiner

Bradley L. Sisson

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1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-10, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1499) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The transmittal page requesting an RCE specifically directs the entry of the response under 37 CFR 1.116, which included an amendment to claim 13. Also indicated is the presence of a "Preliminary Amendment." A review of this "preliminary amendment" finds another amendment to claim 13. This latest version only refers to claim 13 as being "amended," not "twice amended." It is not clear in the record as to why the prior amendment to claim 13 was to be entered and at the same time stricken by the preliminary amendment filed on even date. If the Rule 1.116 amendment was truly to be entered, then the "preliminary amendment" is not of proper order as claim 13 should appear as "twice amended." If claim 13 is to have been amended a second time, as the record so indicates, applicant is requested to resubmit the amendment in proper form. See MPEP 608.01(m).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2-10, 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. See the Office action of 20 March 2001, paper No. 13, for the basis of the rejection.

Response to arguments

4. At page 5 of the response received 15 August 2001 it is asserted that it is not necessary to set a detection limit as such can be done by one of skill in the art. This argument has been fully considered and has not been found persuasive. At issue is whether the specification has enabled the full scope of the claims currently under examination. Claim 13, the sole independent claim, places no limit on the detection limit other than the target DNA and sample exist in a ratio of A/B. Accordingly, claim 13, and all claims that depend therefrom, has been interpreted as encompassing virtually ANY limit of detection. Such breadth of scope has not been found to be adequately enabled by the disclosure and applicant remarks to let one of skill determine the operational limits of the invention unfairly shifts the burden of enablement. In support of this position attention is directed to page 11 of the disclosure where it is written:

However, when the content of the target DNA which is the same as the labeled standard DNA is only 1%, and the assay is conducted at the excessiveness of the sample DNA of 10, the dilution of the labeled standard DNA is 10/11, and the labeled standard DNA is not substantially diluted. Therefore, the DNA whose content is 1% is not detected.

While the method may be governed by certain underlying principles, it is also subject to certain operational limits. No specific value has been ascribed to "A" or "B," accordingly, the claims have been interpreted as though they can be virtually any number. The specification has not set forth a repeatable procedure whereby any level of target nucleic acid can be detected, regardless of how minute it is. Furthermore, the method has not been enabled for the use of any concentration of labeled standard DNA, a component of the assay that is not represented in the equation (A/B).

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Claim 10, drawn to a kit, is also not enabled as the specification sets forth but one method of use and as shown above, the disclosed method is not considered to be enabling. Similarly, reagents identified as being used in such a method are also not enabled.

For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is again applied to the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is 703-308-3978. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Bradley L. Sisson
Primary Examiner
Art Unit 1655

bls
November 4, 2001